

November 13, 2017

BPHC recommendation

Because the NEIDL's BSL-4 permit application is complete and satisfies the regulatory requirements, and BU has responded to the pending information requested by the BPHC and the advisory Boston Biosafety Committee, BPHC staff recommend moving forward with issuing the NEIDL's BSL-4 permit.

Steps since NEIDL received CDC approval in December 2016

- Re-Convened the Boston Biosafety Committee (BBC), the advisory group made up of both scientific experts and community members and appointed by the BPHC Executive Director under the Regulation.
- Appointed two new community members to the BBC: Todd Erceg and Rafael Medina.
- Engaged BSL-4 consultants who have extensive subject matter expertise to assist with inspections, document review, and facilitation of BBC meetings. Held public BBC Meeting on March 6th: 72 individuals attended; 19 provided comments – 18 in support of the NEIDL's BSL-4 permit application, 1 opposed
 - 58 written comments received, 55 in support of permit approval, 3 in opposition
 - BBC reiterated support for the approval of the NEIDL's BSL-4 permit.
- BPHC has fielded a series of public records requests from Klare Allen and Laura Maslow Armand on behalf of Lawyers' Committee for Civil Rights and Economic Justice related to a range of issues including the permit approval process, the roles of all individuals involved in the application review, and emergency preparedness measures. All requests have been answered.
- The interagency Boston Biosafety Working Group, made up of representatives from BU as well as BPHC, Boston EMS, Boston Fire Department, Boston Police Department, has continued to meet to plan and discuss training and drills.
- BU has responded to requests for additional documentation for training for first responders.

Inspections of NEIDL BSL4 laboratory in 2017

- BPHC and BSL-4 consultant Environmental Health and Engineering (EH&E) inspected the NEIDL BSL4 laboratory on May 31, 2017 and submitted an inspection report on August 24, 2017 with requests for additional information related to SOPs.
- Boston University submitted a response to the inspection report on November 2, 2017 with requested information.
- BPHC and EH&E conducted a follow up inspection of the NEIDL BSL-4 laboratory on November 6, 2017. Two research associates were interviewed, the BSL4 laboratory was inspected, researchers demonstrated knowledge of procedures, and SOPs were reviewed. No significant deficiencies were found by BPHC or EH&E.

NEIDL Ramp-up

If approval is issued, there are several next steps that BU would need to take before starting BSL-4 work:

1) Project approval process

- After the initial project, which is included in the BSL-4 lab permit application, all new BSL-4 projects must first be reviewed by BU's Institutional Biosafety Committee.
- Under BPHC guidelines, Boston University is required to notify the Boston City Council and the BPHC Executive Director of any new BSL-4 research project at least thirty (30) days before initiating any BSL-4 research project
 - A draft permit condition further requires notice to BPHC as soon as it is submitted to BU's own Institutional Biosafety Committee.

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- All BSL-4 projects will then be reviewed by the Boston Biosafety Committee, BPHC, and BSL-4 consultants and approved by the BPHC Executive Director before initiation.

2) BSL-4 Laboratory inspection process and frequency and reporting compliance

- BPHC inspects BSL-3 labs at least once per year and BSL-4 labs at least twice per year.
- Any lab working at any biosafety level may be inspected additionally at any time in response to an incident or a safety concern. These inspections can be conducted without prior notification.
- BPHC also has the authority to review any and all documentation related to the operation of a permitted laboratory.
- Each permitted lab must submit an annual report to the BPHC that includes copies of all minutes from the IBC meetings and a complete roster of the IBC's members, a report on any quality assurance and quality improvement efforts during the year, and updated information from the permit application.

• NEIDL must also notify the BPHC each time a new project or program in the lab is submitted for review by the BU IBC and at least thirty days before the project begins.

• Regulations require the immediate reporting of any laboratory incidents which may trigger an inspection or other investigative action. These include:

- Any employee or other individual with access to the lab who has been exposed to high risk agents, shows symptoms of infection, or has been diagnosed with infection;
- Any employee absent from work due to illness for a period of two or more consecutive work days must be evaluated by the institution's Occupational Health Officer before returning to work and, if the Officer suspects the illness may have been related to a lab exposure, the BPHC must be immediately notified; and
- Any failure, malfunction, or renovation of any major mechanical or security system of the lab.

3) Transfer of BSL-4 select agent

- BU will file BSL-4 select agent transfer paperwork with the CDC. At this time, it will be either Ebola or Marburg virus, because those are the only two agents in the project that was sent to BPHC.
- CDC must approve request before shipment can occur. Approval process is estimated to take approximately a month.
- BPHC will notify City agencies of plan for BSL-4 shipment (BFD, BPD, EMS). MA State Police will also be notified.
- BSL-4 agent will be shipped to BU in a dedicated vehicle, using drivers who are background checked, with GPS tracking for packages and truck, at a time known to BPHC and city agencies. Agent will be triple packaged according to Department of Transportation requirements and then packaged in a locked container.
- Truck with BSL-4 agent will arrive at the NEIDL and agent will be moved to the BSL-4 laboratory.
- BPHC and CDC must be notified if there are problems with delivery or shipment.

4) Growing the virus in the laboratory

- Virus will be cultured in the laboratory.

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- Virus inactivation methods will be validated using BSL-4 agent as required by CDC and BPHC.
- Once the validation results are approved by CDC and BPHC, experiments can occur.
- During this time, BPHC and their consultant will continue to review procedures and paperwork for compliance with regulations and the permit documents.
- BPHC staff will receive ongoing training